



Effects of Lycopene and the Mediterranean Diet on Prostate Cancer: A Critical Analysis of the Data

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INTRODUCTION

Prostate cancer (PCa) is one of the most widespread cancers diagnosed in men in the United States and is the second leading cause of cancer-related deaths worldwide [Bray, 2018]. PCa will be a major cancer-related burden both socially and economically in the near future [Bray 2018]. It has been shown that dietary intake of natural anti-inflammatory agents are capable of inhibiting cancer progression [Jang, 1997] [Martínez-Martínez, 2019] [Peisch, 2017] (Figure 1), but due to the nature of dietary studies it is difficult to accurately conclude that diet is capable of impacting chronic diseases and mortality [Schwingshackl, 2017]. This critical analysis aims to collect and evaluate literature focused on prostate cancer progression and the natural anti-inflammatory agents of lycopene and the Mediterranean diet (MedD).

METHODS

Data Sources: An electronic search included the following databases: PUBMED, EBSCOhost Web, Scopus and clinical trials registry platforms were used to survey the important literature.

- Study Categorization:**
- Once studies have been selected, they will be categorized based on the type of study. The categories will be:
 - Randomized Control trials (RCTs)
 - Cohort Studies
 - Case-control studies
 - Cross-sectional studies

RCT Study Selection: Study inclusion criteria were as follows: 1) uniform form of measurement for evaluating the risk of prostate cancer/ current state of prostate cancer in patients; 2) patients treated in a clinical or observational setting; 3) an experimental group in which subjects clearly underwent an intervention focused on preventing or reducing prostate cancer initiation or progression; 4) a clearly defined control group in which subjects received either a placebo or standard care therapy; and 5) an outcome measure assessing the risk or current state of prostate cancer.

Cohort Studies, Case-control Studies, and Cross-Sectional Studies Selection: Study inclusion criteria were as follows: 1) uniform form of measurement for evaluating the risk of prostate cancer/ current state of prostate cancer in patients; and 2) an outcome measure assessing the risk or current state of prostate cancer.

Data Extraction: For randomized control trials a qualitative analysis was done to gather and summarize effects of identified interventions according to the recommended methodology from the Cochrane Handbook [Higgins 2011]. For all other types of studies (Cohort Studies, Case-control studies, and Cross-sectional studies) a rubric of criteria was created and used to analyze these studies (Figure 2).

PROSTATE CANCER TREATMENT

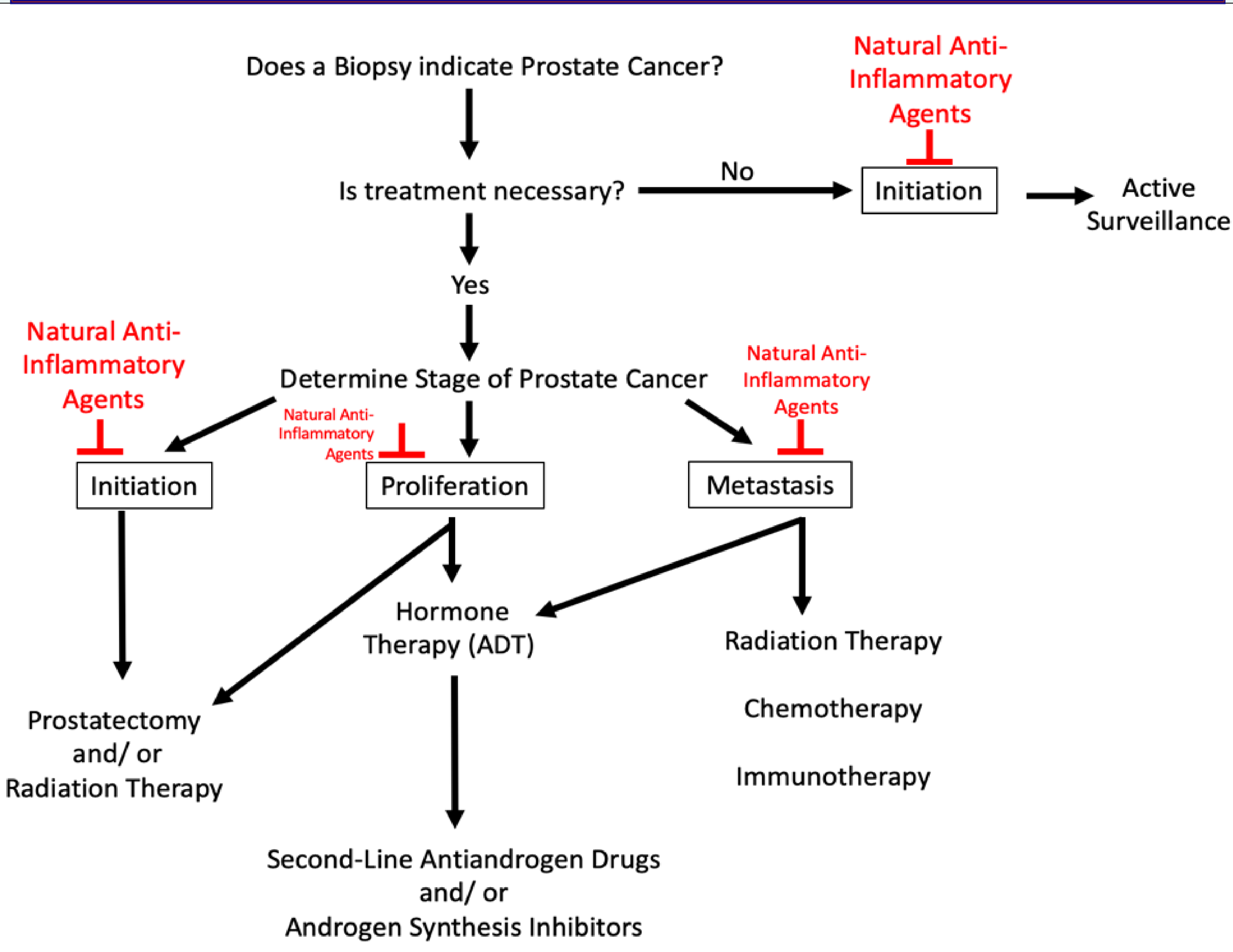


Figure 1: Different treatment options available for prostate cancer and different stages which natural anti-inflammatory agents are capable of effecting cancer progression

CONCLUSION

Conclusions: Despite an insufficiency of high-quality clinical investigations, current literature suggest that: 1) adherence to the MedD may be inhibitory for both PCa incidence and progression, 2) lycopene administration may be inhibitory for PCa incidence, but not progression.

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RUBRIC OF CRITERIA

Domain	Description	High Risk of Bias	Low Risk of Bias	Unclear Risk of Bias	Reviewer Assessment	Reviewer Comments	Article Title
Study Design	Describe the framework and set of methods and procedures used to collect and analyze data	Correlational Design • measures a relationship between two variables without the researcher controlling either of them	Descriptive Study • process of using and analyzing those statistics collected from the experiments performed	Not described in sufficient detail	High Low Unclear		
Confounding Variables	Describe what the different confounder variables were in the experiments as well as how these variables were controlled and to what extent.	Confounding bias is due to having confounding variables in experimental model.	Confounding variables are controlled through, randomization and/or matching and/or restriction	The different potential confounding variables not explained and the ways that researchers controlled for confounding variables were not described in sufficient detail	High Low Unclear		
Statistical Experimental Design	Efficient procedure for planning statistical experiments therefore the data obtained can be analyzed to yield valid and objective results.	Poor statistical design includes, too few subjects, performing incorrect statistical tests, etc.	Statistical experimental design is explained, and all statistical tests are done correctly	Not described in sufficient detail	High Low Unclear		

The below criteria are adapted from the Cochrane Risk Bias tool to fit the needs of this study. Not all research in this area involves random controlled trials, and therefore would not meet all of the criteria from the original Cochrane Risk Bias tool [Higgins, 2011]. The risk bias tool was used as a reference for developing new criteria for purposes of the current study.

Reporting bias Selective reporting	Stated how the possibility of selective outcome reporting was examined by the authors and what was found	Reporting bias due to selective outcome reporting	Selective outcome reporting bias not detected	Insufficient information to permit High judgment ↑	High Low Unclear		
Other bias Other sources of bias	Any important concerns about bias not addressed above*	Bias due to problems not covered elsewhere in the table	No other bias detected	There may be a risk of bias, but there is either insufficient information to assess whether an important risk of bias exists or insufficient rationale or evidence that an identified problem will introduce bias	High Low Unclear		
Attrition bias Incomplete outcome data	Described the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. Stated whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported.	Attrition bias due to amount, nature or handling of incomplete outcome data.	Handling of incomplete outcome data was complete and unlikely to have produced bias	Insufficient reporting of attrition/exclusion to permit judgment (e.g., number randomized not stated, no reasons for High missing data Low provided)	High Low Unclear		

Figure 2: Assessment of Study Bias for Cohort Studies, Case-control Studies, and Cross-Sectional Studies